

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Development and evaluation an Intervention Program for Prevention of Substance Abuse Based on Multi Theory Model(MTM) (in sequential exploratory mixed-method)

Protocol summary

Study aim

Determining the effect of an educational intervention program based on Multi Theory Model on substance abuse prevention.

Design

Quantitative sampling is done in two steps. In instrument psychometric, a sample will be systematically selected randomly from the Morgan table. There is no blinding. In the intervention section, the sample size will be 60 people and available sampling random assignment will be used.

Settings and conduct

In the qualitative phase, interviews will be conducted in the neighborhood mosque. Interviews are conducted as a focus group discussion. In the quantitative phase of the study, the pre-test questionnaire will be completed by visiting the homes of the selected individuals. Then the training program will be implemented and 6 months later the post-test questionnaires will be completed with the procedure of completing the pre-test stage. There is no blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Resident of the neighborhood, age group 15-50 years. Exclusion criteria: Addicted, mentally disabled and unable to cooperate

Intervention groups

The intervention group is trained based on the results of the qualitative stage and with the cooperation of experts who will determine the exact type and duration of the training. The intervention is done through an intervention group based on multi-theory model constructs at least 10 sessions in 6 months. The control group does not take any intervention, but after the end of the study, an educational package is provided to the control group.

Main outcome variables

Initiation of addictive preventive behaviors; Maintaining addiction-preventive behaviors; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200922048805N1**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Nahid Ardian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 7659

Email address

n_ardian1382@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation an Intervention Program for Prevention of Substance Abuse Based on Multi Theory Model(MTM) (in sequential exploratory mixed-method)

Public title

Effectiveness of Interventional Program Based on Multi Theory Model on Prevention of Substance Abuse

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having lived in the neighborhood for at least two years In the age group of 15 to 50 years old, immigrant or native, female or male

Exclusion criteria:

Addicted people (self-report) People with mental disabilities or who unable to participate in the study

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using the stratified randomization method. Samples are divided into control and intervention groups. In addition to sufficient accuracy in the conditions of inclusion criteria, homogenization is based on the variables of age and sex status. Random allocation software is used for randomization. For concealment, we use allocation concealment, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed in a random sequence (Sequentially numbered, sealed, opaque envelopes) in which each of the random sequences created is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the numbering on the outer surface of the envelopes is done in the same way. Finally, the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The present study is carried out by a sequential combination exploratory method including qualitative phase and quantitative phase, in which the intervention is performed in a quantitative phase.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic comitteee of Shahid Sadoughi University of Medical Sciences

Street address

School of Public Health, Shahid Sadoughi Univesity of Medical Sciences , Alem Squ - Shohadaye Gomnam Street, Yazd.Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.SSU.SPH.REC.1398.106

Health conditions studied**1****Description of health condition studied**

Prevention of Substance Abuse Based on Multi Theory Model

ICD-10 code

F19.1

ICD-10 code description

Other psychoactive substance abuse

Primary outcomes**1****Description**

Institutionalization of addiction prevention behaviors among people aged 15 to 50 years

Timepoint

Before and 6 months after the intervention in both groups, the behavior score is measured by completing a questionnaire.

Method of measurement

The score obtained from the designed questionnaire

Secondary outcomes

1

Description

Start preventive behavior from addiction

Timepoint

Before and 6 months after the intervention

Method of measurement

Research made Questionnaire

Intervention groups

1

Description

An intervention group is a group that is randomly selected from the participants and is trained based on the results of the qualitative stage and with the cooperation of experts who will determine the exact type and duration of the training. The content of the training is designed based on the structures of the multi-theory model on the prevention of substance abuse.

Intervention group: The internship is done through group training of at least ten 90-minute sessions over 6 months and with appropriate methods (lectures, questions and answers and the use of educational videos).

Category

Prevention

2

Description

Control group: After the end of the study, three group training sessions are considered for the control group and the educational content is provided to them in the form of brochures and educational videos.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Akramieh neighborhood

Full name of responsible person

Nahid Ardian

Street address

Akramieh neighborhood, Modares Boulevard, Shohade Mehrab Square, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Nahid Ardian

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Social Services

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data related to this research can be shared, such as information about the main result of the study. Of course, this information is done after the applicant's application is reviewed by the council at the University Vice Chancellor for Research. Also, the data will be provided to the applicants after the data owners are not identified.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data of this study are allowed after the permission of Shahid Sadoughi University of Medical Sciences for the analyzes that are to be performed on the data.

From where data/document is obtainable

Social determinants of Health Research Center, School of Health, Shahid Sadoughi University of Medical Sciences, Shohadae Gornam Blvd, Alam Sq. Dr. Seyed Saeed Mazloomi Mahmoodabad 0098 35 38209100 0098 9132506563

What processes are involved for a request to access data/document

The application should be sent to the address listed above in the box. After review, which takes about two to four weeks, the applicant will be contacted after coordination with the Vice-Chancellor for Research and Technology Affairs.

Comments